IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

THE RESEARCH FOUNDATION OF STATE UNIVERSITY OF NEW YORK; NEW YORK UNIVERSITY; GALDERMA LABORATORIES INC.; AND GALDERMA LABORATORIES, L.P., Plaintiffs, v. MYLAN PHARMACEUTICALS INC. Defendant.	C.A. No. 09-184-LPS PUBLIC VERSION
MYLAN PHARMACEUTICALS, INC., Plaintiff, v. GALDERMA LABORATORIES INC.; GALDERMA LABORATORIES, L.P.; AND SUPERNUS PHARMACEUTICALS, INC. Defendants.	C.A. No. 10-892-LPS PUBLIC VERSION

MYLAN'S OPENING POST-TRIAL BRIEF REGARDING REMEDY

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page

CASES

STATUTES

RULES

TABLE OF ABBREVIATIONS

"Amin patents"	Refers collectively to U.S. Patent Nos. 5,789,395 and 5,919,775
"Ashley patents"	Refers collectively to U.S. Patent Nos. 7,211,267 and 7,232,572
"D.I. 892-X"	Refers to a docket entry in Case No. 10-892-LPS
"D.I. 184-X"	Refers to a docket entry in Case No. 09-184-LPS
"Galderma"	Refers to collectively to Plaintiffs the Research Foundation of State University of New York and New York University; Plaintiffs and Declaratory Judgment Defendants Galderma Laboratories Inc., and Galderma Laboratories, L.P.; and Declaratory Judgment Defendant Supernus Pharmaceuticals, Inc.
"Mauro Decl."	Refers to the Declaration of Anthony Mauro
"Mylan"	Refers to Defendant and Declaratory Judgment Plaintiff Mylan Pharmaceuticals Inc.
"Nelson Decl."	Refers to the Declaration of Philip B. Nelson, Ph.D.
"Paragraph IV"	Refers to 21 U.S.C. § 355(j)(2)(A)(vii)(IV)
"Section 271"	Refers to 35 U.S.C. § 271
"532 patent" / "Chang patent"	Refers to U.S. Patent No. 7,749,532

*Please note that all emphasis in quoted excerpts is supplied unless otherwise indicated

I. INTRODUCTION

This case is extraordinary in that, as the Court has now determined, Mylan's Paragraph IV certification has been vindicated. From the date of ANDA application through and past FDA approval, Mylan infringed no patent listed in the Orange Book. The remedies afforded to the parties in this case must account for the extent of the infringement at issue, including the fact that Mylan prevailed on four of the five patents-in-suit and the one patent upon which Galderma prevailed issued well after Mylan filed its ANDA. [redacted]

Under these circumstances, Galderma is not entitled to a permanent injunction. [redacted] Rather, a royalty on future sales is the proper remedy. [redacted]

Further, there is no basis for Galderma's request for an order directing the FDA to convert Mylan's approval from final to tentative. Such relief is available only to claims of

infringement arising from Section 271(e). The parties' claims and defenses regarding the Chang patent arose under the Declaratory Judgment Act and 35 U.S.C. § 271(a) because the Chang patent did not issue until *after* Mylan received FDA approval to launch its ANDA product.

Finally, Mylan requests that the Court enter judgment in its favor on Galderma's exceptional case allegations because those claims are mooted by the August 26, 2011 opinion.

II. GALDERMA IS NOT ENTITLED TO A PERMANENT INJUNCTION

Galderma is not entitled to a permanent injunction because the relevant factors weigh decidedly against issuance of such an injunction. In *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006), the Supreme Court overruled the Federal Circuit's "general rule that courts will issue permanent injunctions against patent infringement absent exceptional circumstances." "According to well-established principles of equity, a plaintiff seeking a permanent injunction must satisfy a four-factor test before a court may grant such relief. A plaintiff must demonstrate: (1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction." *Id.*

Galderma bears the burden of proof. A permanent injunction will be denied if patentee does not meet its burden. *See, e.g., Bard Peripheral Vascular, Inc. v. W.L. Gore & Assoc. Inc.*, No. CV-03-0597-PHX-MHM, 2009 WL 920300, *5 (D. Ariz. Mar. 31, 2009) (finding monetary damages adequate to compensate for willful infringement and denying permanent injunction); *Advanced Cardiovascular Sys., Inc. v. Medtronic Vascular, Inc.*, 579 F. Supp. 2d 554, 558-562 (D. Del. 2008) (denying motion for permanent injunction where plaintiff failed to prove irreparable harm, inadequacy of monetary damages, or public interest). The fact that Mylan

prevailed on four of the five patents-in-suit and the fact that the Chang patent did not issue until well after Mylan filed its ANDA weigh against a permanent injunction.

A. Galderma Will Not Be Irreparably Harmed or Encounter Injury That Cannot Be Adequately Compensated By Money Damages

The first two *eBay* factors weigh decidedly against injunctive relief due to the Court's determination that Mylan prevailed on the Ashley and Amin patents.[1] [redacted]

To the extent Galderma attempts to articulate types of harm that it will face in the absence of a permanent injunction, its arguments fall short because they likely would have suffered those harms without any ability to seek recovery but for the preliminary injunction. Moreover, the Court's finding that Mylan's ANDA product infringes the Chang patent, by itself, is insufficient to warrant injunctive relief because the Court has previously held that "[i]nfringing one's right to exclude, alone, is insufficient to warrant injunctive relief." *Telcordia Techs., Inc. v. Cisco Sys., Inc.*, 592 F. Supp. 2d 727, 747-8 (D. Del. 2009), *aff'd in part, vacated in part,* 612 F.3d 1365 (Fed. Cir. 2010) (quoting *IMX, Inc. v. LendingTree, LLC*, 469 F. Supp. 2d 203, 225 (D. Del. 2007)); *see also z4 Techs., Inc. v. Microsoft Corp.*, 434 F. Supp. 2d 437, 441 (E.D. Tex. 2006) ("[A] violation of the right to exclude does not inevitably lead to the conclusion that a

[1] As the Court noted in the August 26, 2010 opinion, "[t]he ***extent*** of the infringement . . . may be relevant to the proper remedy to be accorded to Galderma." D.I. 892-149 at 64 footnote 27.

patent holder cannot be adequately compensated by remedies at law such as monetary damages without first applying the principles of equity.").

In addition, the circumstances present here provide no "specific reasons why [Mylan's] infringement cannot be compensated for with a money award." *Praxair, Inc. v. ATMI, Inc.*, 479 F. Supp. 2d 440, 444 (D. Del. 2007) (no permanent injunction where patentee failed to prove money damages were insufficient). Courts have previously found that damages in the form of an ongoing royalty, rather than an injunction, provide adequate compensation under the appropriate circumstances. *See Bard Peripheral*, 2009 WL 920300 at *5 ("[T]he Court can impose a compulsory license on the continued sales of [defendant's] infringing products for the remainder of the life of the [] patent. Certainly, money damages are not the perfect remedy for Plaintiffs; . . . Perfection, however, is not the Court's goal with respect to damages, adequacy is.") (internal citations omitted).

The Federal Circuit has similarly held that "[u]nder some circumstances, awarding an ongoing royalty for patent infringement in lieu of an injunction may be appropriate." *Paice LLC v. Toyota Motor Corp.*, 504 F.3d 1293, 1314 (Fed. Cir. 2007). Those circumstances are present here. [redacted] Money damages in the form of a royalty would provide adequate compensation for any ongoing harm that Galderma would suffer, [redacted]; 35 U.S.C. § 284. The precise royalty percentage could be ascertained through the application of well-known and established methodologies. *See* Nelson Decl., ¶ 18.

B. The Balance Of Hardships Weighs Against A Permanent Injunction

The third *eBay* factor also weighs against a permanent injunction. The Court determined that Mylan does not infringe the Ashley or Amin patents, yet Galderma was able to use the Ashley patents and this litigation to obtain a preliminary injunction. [redacted] This is especially true in light of the fact that Mylan prevailed on four of the five patents-in-suit, and that Mylan's ANDA was filed nearly two years before the Chang patent issued.

C. The Public Interest Would Not Be Served By A Permanent Injunction

The public interest would not be served by a permanent injunction. In the context of generic pharmaceuticals, courts have acknowledged the public interest in making generic drugs available to the public. "[T]he public has a strong interest in obtaining generic drugs at the reduced rates that they are offered. This strong public interest has been recognized in the enactment of the Hatch-Waxman Amendments, whose principal purpose was 'to increase competition in the drug industry by facilitating the approval of generic copies of drugs.' 'Congress expected that competition "to make available more low cost generic drugs."'" *CollaGenex Pharms., Inc. v. IVAX Corp.*, 375 F. Supp. 2d 120, 141 (E.D. N.Y. 2005) (citations omitted); *see also Boehringer Ingelheim Corp. v. Shalala*, 993 F. Supp. 1, 3 (D.D.C. 1997). (recognizing public interest in "receiving generic competition to brand-name drugs as soon as is possible"). "It is good public policy to foster the development and distribution of new drugs and associated medical devices, through the fair and effective enforcement of our patent laws and the

Hatch-Waxman addition to those laws." *Advanced Cardiovascular Sys., Inc. v. Medtronic Vascular, Inc.*, No. C95-03577-DLJ, 2008 WL 4647384, *11(N.D. Cal. Oct. 20, 2008) (noting negative market effect of an injunction and denying permanent injunction); *see also In re Barr Labs., Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991) ("Congress sought to get generic drugs into the hands of patients at reasonable prices-fast.").

A permanent injunction would disserve patients because they will be denied the opportunity to buy lower-priced generic doxycycline delayed-release capsules and have no choice but to spend additional dollars to purchase the branded product. *See* Nelson Decl., ¶ 24. The incentives of Mylan and other generic suppliers to develop low-priced pharmaceuticals that compete with branded drugs are undermined by a policy that liberally grants permanent injunctions to branded companies whose patents issue well after a generic company has filed its ANDA, as is the case with the Chang patent. *Id.*, ¶ 25. On the other hand, denial of a permanent injunction would increase accessibility to rosacea treatment through the affordability of a generic. *Id.*, ¶ 24. There will be a significant number of additional prescriptions for generic doxycycline from new rosacea drug users who will turn to Mylan's product at the lower generic price point but would not otherwise have tried Oracea®. *Id.*

All of the *eBay* factors weigh against a permanent injunction; therefore, Mylan respectfully requests that the Court deny Galderma's request for injunctive relief. Mylan also requests the Court to order the parties to submit additional briefs and evidence regarding the appropriate royalty on Mylan's future sales.

III. [redacted]

[redacted]

B. [redacted]

[redacted]

[redacted]

[redacted]

[redacted]

2 [redacted]

[redacted]

IV. GALDERMA IS NOT ENTITLED TO RELIEF UNDER 35 U.S.C. § 271(e)(4).

In its Opening Post-Trial Brief, Galderma requested, under Section 271(e)(4)(A), an order directing the FDA to change the effective date of FDA approval for ANDA 90-855 to the day after expiration of the Chang patent. Galderma also requested, under Section 271(e)(4)(B), a permanent injunction against Mylan with respect to Mylan's ANDA product. D.I. 892-138/D.I. 184-267 at 30. No such relief, however, is available to Galderma because the parties' claims and defenses regarding the Chang patent do not arise under Section 271(e)(2). *See* 35 U.S.C. §§ 271(e)(2) and 271(e)(4)(A) & (B).

A Paragraph IV certification is a necessary predicate for an infringement action under Section 271(e)(2). Mylan's ANDA does not include a Paragraph IV certification as to the Chang patent because the Chang patent did not issue until July 6, 2010 and was listed in the Orange Book a few days later – *i.e.*, ***after*** the FDA granted final approval to Mylan's ANDA product on July 1, 2010. *See* 21 C.F.R. 314.94(a)(12)(viii)(C)(2) ("An applicant is not required to amend a

submitted [Paragraph IV] certification when information on a patent on the listed drug is submitted after the effective date of approval of the abbreviated application."). Thus, the parties' claims and defenses regarding the Chang patent arise under the Declaratory Judgment Act. *See, e.g.*, D.I. 892-1 (Mylan's DJ Complaint).

Because there was no Paragraph IV certification as to the Chang patent, there can be no finding of infringement under Section 271(e)(2) and no relief under Section 271(e)(4).

V. JUDGMENT SHOULD BE ENTERED IN FAVOR OF MYLAN ON GALDERMA'S EXCEPTIONAL CASE CLAIMS

Finally, Mylan respectfully requests that the Court enter judgment in its favor on Galderma's exceptional case claim in Case No. 09:184 because the Court found that Mylan does not infringe any claim of the Ashley or Amin patents, and that the Amin patents are invalid. Mylan also requests that the Court enter judgment that Galderma is not entitled to recover attorney's fees associated with its claims.

In addition, the record before the Court cannot justify recovery of attorneys' fees by Galderma on its exceptional case claim regarding the Chang patent. Mylan, therefore, requests that the Court also enter judgment in Mylan's favor on those claims in Case No. 10:892. *See* 35 U.S.C. § 285.

VI. CONCLUSION

For the foregoing reasons, Mylan respectfully requests that the Court issue an Order: (1) denying a permanent injunction; (2) providing for determination of a reasonable royalty to be paid by Mylan to Galderma for future Mylan sales pending appeal; [redacted]; (4) denying Galderma's request for relief under 35 U.S.C. §§ 271(e)(4)(A) and (B); and (5) entering judgment in Mylan's favor on all of Galderma's exceptional case claims.

Respectfully,

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CERTIFICATE OF SERVICE

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